

**The Conseco Brand Sea Buckthorn Seed Oil  
Towards  
Pre-market Notification for Dietary Supplement Substance in USA**

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Susan Walker, M.D.,  
Acting Director,  
Division of Dietary Supplements Programs,  
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820),  
Center for Food Safety and Applied Nutrition,  
Food and Drug Administration,  
5100 Paint Branch Parkway, College Park, MD 20740  
Telephone number: 301 436- 2375

*OKB/FDA*

Dear FDA Officer Dr. Susan Walker - Acting Director,

**Subject: Conseco Brand Sea Buckthorn Seed Oil towards 75-Day Pre-market Notification  
for Dietary Supplement Substance in USA**

Thank you for your reading.

We are Conseco Sea buckthorn Co., Ltd.. Right now, we submit the documents about "Conseco Brand Sea Buckthorn Seed Oil towards 75-Day Pre-market Notification for Dietary Supplement Substance in USA" to FDA CFSAN. Please relevant Officers review the documents according to "Federal Food, Drug, and Cosmetic Act" of USA, and tell us all of your viewpoints, in order to let us finish the whole notification process of the product.

Thank you for your considering.

We are looking forward to hearing from you as soon as possible.

Sincerely yours,

*Han Xu*  
Han Xu, M.D.  
Senior Researcher

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## Overview - The Conseco Brand Sea Buckthorn Seed Oil

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### **My name and complete address:**

Han Xu, M.D.

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### **The name of the new dietary supplement:**

The Conseco Brand Sea Buckthorn Seed Oil

### **The description of the dietary supplement substance:**

This is the 100% natural herbal dietary supplement substance obtained from the botanical seeds of Sea buckthorn (*Hippophae rhamnoides* L.). Like as the material substance of dietary supplement, we recommend that the product can be used into the Soft Capsule of Sea Buckthorn Seed Oil about dose 3g per day [Specification: 0.45-0.5g/capsule] [Dosage: 2-3 capsules/time, 2 times/day].

### **Our products abide by following P. R. China Industry Standards:**

Sea buckthorn Seed Oil

The Industry Standards of P. R. China

HB/QS 002—94

1994—06—08 Published

1994—10—17 Implemented

Published by National Sea buckthorn Coordination Office

**[ Detailed in Document Digest (P-2) ]**

Green Trade Standards of Importing & Exporting Medicinal Plants & Preparations

P. R. China Foreign Trade Industry Standards

WM2-2001

2001—04—23 Published

2001—07—01 Implemented

Published by Ministry of Foreign Trade and Economic Cooperation, PRC

(Ministry of Commerce P. R. China)

**[ Detailed in Document Digest (T) ]**

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## Overview - The Conseco Brand Sea Buckthorn Seed Oil

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### The level of the dietary ingredients in the product:

**Dietary Ingredients:** Total Unsaturated Fatty,  $\geq 85\%$ .

Sub-Oleic Acid, Flax Acid & Oleic Acid in Total Unsaturated Fatty,  $\geq 90\%$ .

Sub-Oleic Acid & Flax Acid in Total Unsaturated Fatty,  $\geq 65\%$ .

Vitamin E (mg/100g) ,  $\geq 100$ .

$\alpha$  - tocopherol (mg/100g) ,  $\geq 30$ .

### The conditions of use of the product:

Like as the botanical material substance of dietary supplement, we recommend that the product can be used into the Soft Capsule of Sea Buckthorn Seed Oil about dose 3g per day [**Specification:** 0.45-0.5g/capsule] [**Dosage:** 2-3 capsules/time, 2 times/day].

### The label contents of the product:

**Brand Name:** Conseco Brand.

**Product Name:** Sea Buckthorn Seed Oil.

**Serving Size:** 100ml/bottle, 4.0 liter/barrel, or according to customer requirements.

**Dietary Ingredients:** Total Unsaturated Fatty,  $\geq 85\%$ .

Sub-Oleic Acid, Flax Acid & Oleic Acid in Total Unsaturated Fatty,  $\geq 90\%$ .

Sub-Oleic Acid & Flax Acid in Total Unsaturated Fatty,  $\geq 65\%$ .

Vitamin E (mg/100g) ,  $\geq 100$ .

$\alpha$  - tocopherol (mg/100g) ,  $\geq 30$ .

**Recommendation:** Like as the botanical material substance of dietary supplement, we recommend that the product can be used into the Soft Capsule of Sea Buckthorn Seed Oil about dose 3g per day [**Specification:** 0.45-0.5g/capsule] [**Dosage:** 2-3 capsules/time, 2 times/day].

**Claim:** This is the 100% natural herbal dietary supplement. The statement has not been evaluated or approved by the FDA of USA. The product is not intended to diagnosis, treat, cure, or prevent any disease.

**Alert:** Keep out children. Forbid in diarrhea.

**Store:** Store at a cool & dry location.

**Distributor:** Conseco Sea buckthorn Co., Ltd.

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## Overview - The Conseco Brand Sea Buckthorn Seed Oil

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### The history of use like as herbal extraction in P. R. China:

According to the Implemented Date of the P. R. China Industry Standards as following:

Sea buckthorn Seed Oil

The Industry Standards of P. R. China

HB/QS 002—94

1994—06—08 Published

1994—10—17 Implemented

Published by National Sea buckthorn Coordination Office

The history of the product used like as herbal extraction in P. R. China should be beginning in 1994-10-17 officially.

### The other evidences of safety tests:

The recommended human usage for Sea buckthorn Seed Oil is 3g per day on our product label. This dosage does not present any safety concerns. According to 7-days acute toxic test and 90-days long-term test, the results cannot determine LD50 dosage in ICR mice and SD rats actually. But the results can indicate that, in 7-days acute toxicity test towards ICR mice, LD50>60ml/Kg.BW (equivalent to 57.6g/Kg.BW); in 7-days acute toxicity test towards SD rats, LD50>20ml/Kg.BW (equivalent to 19.2g/Kg.BW). (BW means body weight of animals.) The dosages used in the 90-days long-term toxicity studies, 2ml/Kg.BW, 5ml/Kg.BW, and 10ml/Kg.BW are equivalent to 12, 30, 60 times of human using dosage (in P. R. China) - [10ml (9.6g) per day, average human body weight 60Kg]. Towards our recommended human usage for Sea buckthorn Seed Oil, 3g per day, the safety is enough.

### Acute toxicity test for Sea buckthorn seed oil

Animal species: Little white mice, ICR species of body weight 18-22g; SD rats, SD species of body weight 140-180g; are supplied by Laboratory Animal Center, Xian Medical University in Shanxi Province. The 7-days acute toxicity tests have been done by Pharmacy Department, Xian Medical University.

(a) The 60 ICR little white mice, body weight 18-22g, are divided three groups, each group has 20 mice; control group mice are fed for water; the other two groups are fed Sea buckthorn seed oil for low dose (30ml/Kg.BW) and high dose (60ml/Kg.BW) (divide 2 ingestions, interval 6 hours). After observe one week, the study doesn't find any mice death. At the first day, most mice presents with diarrhea and appetite decrease; the rest six days, every mouse is normal activity and appetite, and has no diarrhea. Therefore the 7-days study can not measure LD50 in mice under the conditions. Until 8th day, do autopsy, the results show that there are no significant difference

## Overview - The Conseco Brand Sea Buckthorn Seed Oil

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comparison to control group; there are no macroscopic pathological changes in heart, liver, spleen, lung, and kidney in the experimental group mice.

(b) In the second part of 7-days acute toxic experiment in SD rats, SD species of body weight 140-180g, half male, half female; 30 rats are divided three groups, each group has 10 rats. The 10 control group rats are fed water; another two groups rats are fed Sea buckthorn seed oil for low dose (10ml/Kg.BW) and high dose (20ml/Kg.BW). The acute toxicity experiment can be understood that the first time ingestion of 5ml and 10ml/Kg.BW in Sea buckthorn seed oil for 20 rats, and after 6 hour, each group rats received another dosage 5ml/Kg.BW and 10ml/Kg.BW. After observe one week, they don't find any rats death. At the first day, some rats' appetite decrease and daily activity decrease; the rest six days, every rat is normal activity. Therefore the study cannot measure LD50 in rats under the conditions.

### Long-term toxic experiment:

(c) In the third part of 90-days long-term toxic experiment in SD rats, SD species of body weight 130-180g, half male, half female, total 80 SD rats. They continue to feed each mice for 90 days, 80 SD rats are divided into three groups for experiment and another group for control; each group contains 20 rats. Control group rats received water, experimental group rats received 2ml/Kg.BW, 5ml/Kg, 10ml/Kg Sea buckthorn Seed Oil (1 ingestion per day, equal to 12, 30, and 60 times of human using dosage in P. R. China). After observing for 90 days, there are no death. About hair growth and behavior change in the three experiment groups, there is no significant difference comparison by control group. About body weight, balance BW each time per 10 days, there is no significant difference comparison by control group ( $p>0.05$ ). Also they do the blood test including HB, RBC, WBC indexes, all the blood test are in the normal range. There is no significant difference comparison by control group rats ( $P>0.05$ ). As well as they do the blood index test, including SGPT and BUN, all test results are in the normal range, there is no significant difference comparison to control group rats ( $P>0.05$ ). There are no macroscopic pathological changes in the heart, liver, spleen, kidney, adrenal gland, testis, womb & oval gland, and thymus gland, all organ weight are in the normal range, there is no significant difference comparison to control group mice ( $P>0.05$ ). The dosages in the three experiment groups used in the 90-days toxicity studies, 2ml/Kg.BW, 5ml/Kg, 10ml/Kg are equivalent to 12, 30, 60 times of using dosage (10ml per day or 9.6g per day) in human (in P. R. China). Therefore the study can not get LD50 in SD rats under the conditions.

### [ Detailed in Literature Digest (P-2) ]

## Overview - The Conseco Brand Sea Buckthorn Seed Oil

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Other adverse substances are limited by following P. R. China Industry Standards:

Sea buckthorn Seed Oil

The Industry Standards of P. R. China

HB/QS 002—94

1994—06—08 Published

1994—10—17 Implemented

Published by National Sea buckthorn Coordination Office

**[ Detailed in Document Digest (P-2) ]**

Green Trade Standards of Importing & Exporting Medicinal Plants & Preparations

P. R. China Foreign Trade Industry Standards

WM2-2001

2001—04—23 Published

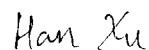
2001—07—01 Implemented

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**[ Detailed in Document Digest (T) ]**

**My signature by myself you can contact me if you have any questions**



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Sea buckthorn Seed Oil

The Industry Standards of P. R. China

HB/QS 002—94

1994—06—08 Published

1994—10—17 Implemented

Published by National Sea buckthorn Coordination Office

Table 1 Appearance Indexes

Item	Index
Description	Brown yellow or brown red transparent liquid.
Odor & Taste	Sea buckthorn Seed Oil inherent flavour, no offodour.

Table 2 Indexes of Physics And Chemistry

Item	Index
Density (20℃)	0.8900—0.9550
Refractive Index (20℃)	1.4650—1.4800
Acid value (mg KOH/g), ≤	40
Iodin value (g/100g)	130—200
Saponification value (mg KOH/g)	184—210
Nonsaponification (%) ≥	1
Moisture (%), ≤	0.3
Vitamin E (mg/100g), ≥	100
α - tocopherol (mg/100g), ≥	30

Table 3 Hygiene Indexes

Item	Index
As (ppm), ≤	0.1
Hg (ppm), ≤	0.05
Peroxy Value (ex factory, %), ≤	0.40
Residue Solvent (ppm)	0

## Attachments

### --- Document Digest (T) ---

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P. R. China Foreign Trade Industry Standards

WM2-2001

Ministry of Foreign Trade and Economic Cooperation, PRC

(Ministry of Commerce P. R. China)

2001-04-23 Published

2001-07-01 Implemented

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#### 4. Limited Quantity Indexes

4. 1. Heavy Metal and Arsenate

4. 1. 1. Total Heavy Metal  $\leq 20.0$  mg/kg

4. 1. 2. Pb  $\leq 5.0$  mg/kg

4. 1. 3. Cd  $\leq 0.3$  mg/kg

4. 1. 4. Hg  $\leq 0.2$  mg/kg

4. 1. 5. Cu  $\leq 20.0$  mg/kg

4. 1. 6. As  $\leq 2.0$  mg/kg

4. 2. Aflatoxin Content

4. 2. 1. B1(Aflatoxin)  $\leq 5$   $\mu$  g/kg

4. 3. Pesticide Residual Quantity

4. 3. 1. BHC  $\leq 0.1$  mg/kg

4. 3. 2. DDT  $\leq 0.1$  mg/kg

4. 3. 3. PCNB  $\leq 0.1$  mg/kg

4. 3. 4. Aldrin  $\leq 0.02$  mg/kg

4. 4. Microbiology Indexes: Escherichia coli -- 0/g or 0/ml

Staphylococcus aureus -- 0/g or 0/ml

Pseudomonas aeruginosa -- 0/g or 0/ml

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## Attachments

### --- Literature Digest (P-2) ---

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An experimental study of toxicity of Hippophae rhamnoides L. seed oil

Che Xi-Ping, Guan Xiao-Hong, Guo Feng, Tang Cheng-Han

Pharmacy Department, Xian Medical University, Xian 710061

Hippophae 1996.03; 9(1): 38-41

**Material Sample:** Sea buckthorn (SB) (Hippophae rhamnoides L.) Seed Oil. Density is 0.96g/ml.

**Animal:** ICR mice, SD rats. Closed animal community; Supplied by Laboratory Animal Center, Xian Medical University

#### **Methods and Results:**

According to 7-days acute toxic test and 90-days long-term toxic test, the article cannot determine LD50 dosage in ICR mice and SD rats actually. But the results can indicate that, in 7-days acute toxicity test towards ICR mice, LD50>60ml/Kg.BW (equivalent to 57.6g/Kg.BW), and in 7-days acute toxicity test towards SD rats, LD50>20ml/Kg.BW (equivalent to 19.2g/Kg.BW). (BW means body weight of animals.) The dosages in the three experimental groups used in the 90-days long-term toxicity studies, 2ml/Kg.BW, 5ml/Kg.BW, and 10ml/Kg.BW are equivalent to 12, 30, 60 times of human using dosage (should be 10ml or 9.6g per day, average human BW 60Kg) (in P. R. China). All the results of the experimental groups in the 90-days long-term toxicity studies show that there is no significant difference comparison to control group. There are no macroscopic pathological changes in major organs.

#### ● Acute toxicity test:

Towards ICR mice:

The 60 ICR little white mice, body weight (BW) 18-22g, half male, half female, are divided three groups random according to body weight and sex, and each group has 20 mice. After fasting 14 hours, group 1 and group 2 mice are fed for Sea buckthorn Seed Oil low dose (30ml/Kg.BW) and high dose (60ml/Kg.BW). Control group, group 3 mice are fed for water. (Morning and afternoon, 2 times per day; with injection gastric, ig, each time; interval 6 hours.) Total each mouse (group 1 and group 2) can be received above whole doses. Divide cages and foster crowds with same conditions, solid feedstuff and normal drink. Observe 7 days at room temperature, and record animal changes and death. At the day 1, most mice presents with light diarrhea, activity and appetite decrease, and oiliness dejecta; the high dose group is more obvious; day 2 - day 3, appetite, defecation, and activity recover gradually; there is no significant difference comparison with control group. The experiment doesn't find any mice death. Therefore the study cannot measure LD50 in mice actually under the conditions. But the results indicate: LD50>60ml/Kg.BW in ICR mice. Until day 8, end experiment, do autopsy, the results show that there is no significant difference comparison to control group; there are no obvious pathological changes in the major organs of heart, liver, spleen, lung, and kidney in the experimental group mice.

## Attachments

### --- Literature Digest (P-2) ---

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#### Towards SD rats:

In the second part of acute toxic experiment in SD rats, SD species of body weight 140-180g, half male, half female; 30 rats are divided three groups random according to body weight and sex, each group has 10 rats. After fasting 15 hours, the control group rats (group 3) are fed water; another two groups rats (group 1 and group 2) are fed Sea buckthorn seed oil for low dose (10ml/Kg.BW) and high dose (20ml/Kg.BW). (Morning and afternoon, 2 times per day; with injection gastric, ig, each time; interval 6 hours.) Total each rat (group 1 and group 2) can be received above whole doses. Divide cages and foster crowds with same conditions, solid feedstuff and normal drink. Observe 7 days at room temperature, and record animal changes and death. At the day 1, the rats' appetite and daily activity decrease. The high dose group rats appear oiliness dejecta. After day 2, appetite, defecation, and activity recover gradually; there is no significant difference comparison with control group. After observe the experiment, the results don't find any rats death in all of groups. Therefore the study cannot measure LD50 in rats actually under the conditions. But the results indicate: LD50>20ml/Kg.BW in SD rats.

#### ● Long-term toxic experiment in SD rats

In the long-term toxic experiment in SD rats, SD species of weight 130-180g; half male, half female, total 80 SD rats. After feed one week in laboratory conditions and be divided four groups random according to body weight and sex, 80 SD rats are divided into three groups (group 2, group 3, group 4) for experiment and another group for control (group 1); each group contains 20 rats. The control group rats (group 1) received water 10ml/Kg.BW; experimental group rats (group 2, group 3, and group 4) received Sea buckthorn seed oil with injection gastric, ig, 2ml/Kg.BW, 5ml/Kg.BW, and 10ml/Kg.BW [equal to 12, 30, and 60 times of human using dosage with body weight (in P. R. China)], each time per day and continue to feed each rat for 3 months. Divide cages and foster crowds with same conditions, solid feedstuff and normal drink. The rats are measured body weight per 10 days, and observed activity, appetite, dejecta, and hair color. After observing for 3 months, there is no significant difference comparison by control group ( $p>0.05$ ) in body weight (Table 1), and there is no death. About hair color and behavior change in the three groups, there is no significant difference comparison by control group, except some high dose group rats have soft dejecta, light yellow hair, and a little appetite decrease. Also they do the blood tests, including HB, RBC, and WBC indexes (Table 2), all the blood tests are in the normal range. There is no significant difference comparison by control group SD rats ( $P>0.05$ ). As well as they do other blood index tests, including SGPT (Table 3) and BUN (Table 4), all test results are in the normal range, and there is no significant difference comparison to control group SD rats ( $P>0.05$ ). There are no macroscopic pathological changes in the heart, liver, spleen, kidney, adrenal gland, testis, womb & oval gland, and thymus gland, all organ weights (Table 5) are in the normal ranges, and there is no significant difference comparison to control group SD rats ( $P>0.05$ ).

## Attachments

### --- Literature Digest (P-2) ---

[Attend in following tables in the long-term toxic experiment in SD rats: **group 1**, control group, received water 10ml/Kg.BW per day; **group 2**, low dose group, received Sea buckthorn seed oil 2ml/Kg.BW per day; **group 3**, middle dose group, received Sea buckthorn seed oil 5ml/Kg.BW per day; **group 4**, high dose group, received Sea buckthorn seed oil 10ml/Kg.BW per day.]

Table 1 - Sea buckthorn Seed Oil towards SD rat body weight (BW)

Group	Dosage of SB Seed Oil (ml/Kg.BW)	Animal amount	Body weight (BW) (g • average ± sd)			
			Before received ig	After received ig (days)		
				30	60	90
Group 1	--	20	165.3 ± 20.3	227.9 ± 19.8	269.3 ± 32.1	296.4 ± 34.6
Group 2	2	20	166.6 ± 16.8	225.7 ± 28.2	275.7 ± 30.5	306.4 ± 31.6
Group 3	5	20	168.1 ± 16.3	224.0 ± 15.3	267.4 ± 21.5	291.4 ± 25.9
Group 4	10	20	161.4 ± 17.5	222.8 ± 28.1	261.2 ± 25.3	288.7 ± 39.7

Note: group received Sea buckthorn seed oil comparison by control group P>0.05

The ig, injection gastric, means pouring into stomach via mouth.

Table 2 - Sea buckthorn Seed Oil towards SD rat blood indexes

Group	Animal amount	Hb (g/L)	RBC (10 <sup>12</sup> /L)	WBC (10 <sup>9</sup> /L)	WBC Classify	
					Neutrophilic Granulocytes	Lymphocytes
Group 1	20	117.6 ± 19.3	7.9 ± 0.4	11.9 ± 1.6	0.27 ± 0.07	0.70 ± 0.09
Group 2	20	104.4 ± 18.1	7.8 ± 0.9	12.1 ± 2.1	0.29 ± 0.07	0.69 ± 0.07
Group 3	20	105.7 ± 16.6	7.9 ± 1.1	12.5 ± 2.0	0.27 ± 0.07	0.72 ± 0.08
Group 4	20	115.7 ± 11.0	8.1 ± 0.6	12.4 ± 2.4	0.27 ± 0.08	0.71 ± 0.09

Note: group received Sea buckthorn seed oil comparison by control group P>0.05

Table 3 - Sea buckthorn Seed Oil towards SD rat SGPT

Group	Dosage of SB		Animal amount	SGPT (u) average ± sd	P Value
	Seed Oil (ml/Kg.BW)				
Group 1	--		20	49.1 ± 10.8	--
Group 2	2		20	53.2 ± 8.6	>0.05
Group 3	5		20	51.5 ± 14.0	>0.05
Group 4	10		20	52.4 ± 15.3	>0.05

## Attachments

### --- Literature Digest (P-2) ---

[Attend in following tables in the long-term toxic experiment in SD rats: **group 1**, control group, received water 10ml/Kg.BW per day; **group 2**, low dose group, received Sea buckthorn seed oil 2ml/Kg.BW per day; **group 3**, middle dose group, received Sea buckthorn seed oil 5ml/Kg.BW per day; **group 4**, high dose group, received Sea buckthorn seed oil 10ml/Kg.BW per day.]

Table 4 - Sea buckthorn Seed Oil towards SD rat BUN

Group	Dosage of SB Seed Oil (ml/Kg.BW)	Animal amount	SD rat BUN (average $\pm$ sd)		
			mg %	mmol/L	P Value
Group 1	--	20	16.23 $\pm$ 2.40	5.79 $\pm$ 0.86	--
Group 2	2	20	14.29 $\pm$ 2.38	5.10 $\pm$ 0.85	>0.05
Group 3	5	20	17.89 $\pm$ 2.97	6.39 $\pm$ 1.06	>0.05
Group 4	10	20	16.94 $\pm$ 2.39	6.05 $\pm$ 0.85	>0.05

Table 5 - Sea buckthorn Seed Oil towards SD rat major organs' wet weight

Organ	major organ wet weight/body weight (g/100g, n=20, Average $\pm$ SD )			
	Group 1	Group 2	Group 3	Group 4
Heart	0.35 $\pm$ 0.04	0.38 $\pm$ 0.09	0.34 $\pm$ 0.07	0.35 $\pm$ 0.08
Liver	3.58 $\pm$ 0.18	3.71 $\pm$ 0.69	3.66 $\pm$ 0.32	3.50 $\pm$ 0.52
Spleen	0.25 $\pm$ 0.08	0.27 $\pm$ 0.07	0.27 $\pm$ 0.08	0.29 $\pm$ 0.12
Kidney	0.70 $\pm$ 0.17	0.68 $\pm$ 0.08	0.66 $\pm$ 0.08	0.68 $\pm$ 0.13
Testis	1.12 $\pm$ 0.18	1.13 $\pm$ 0.23	1.14 $\pm$ 0.10	1.11 $\pm$ 0.15
Womb & Oval Gland	0.31 $\pm$ 0.05	0.29 $\pm$ 0.07	0.32 $\pm$ 0.03	0.29 $\pm$ 0.09
Thymus Gland	0.10 $\pm$ 0.04	0.10 $\pm$ 0.03	0.12 $\pm$ 0.04	0.10 $\pm$ 0.02
Adrenal Gland (mg/100g)	13.89 $\pm$ 3.03	14.16 $\pm$ 3.88	14.35 $\pm$ 4.43	14.91 $\pm$ 3.27

Note: group received Sea buckthorn seed oil comparison by control group P>0.05

(Testis should be n=10; Womb and Oval Gland should be n=10.)